

REMARKS/ARGUMENTS

Favorable reconsideration of this application as presently amended and in light of the following discussion is respectfully requested.

Claims 1-13 are now pending in this application. Claims 12 and 13 have been added by the present amendment. Support for the added claims is found at least at paragraphs 0056 and 0057 on pages 9 and 10, and at paragraphs 0076 and 0077 on page 14 of the Specification.

In the outstanding Office Action, Claims 1-11 were rejected under the doctrine of nonstatutory double patenting over claims 1-15 of U.S. Patent No. 6,641,525. Claim 10 was rejected under 35 U.S.C. § 102(b) as anticipated by Semrad, U.S. 5,234,438. Claims 1-10 were rejected under 35 U.S.C. § 102(e) as anticipated by Lehe, U.S. 6,273,852. The Specification and an Information Disclosure Statement filed on July 11, 2003 were objected to. Claim 11 has been indicated as being allowable. Applicants acknowledge with appreciation the indication of allowable subject matter.

Claim 10 was rejected under 35 U.S.C. § 102(b) as anticipated by Semrad, U.S. 5,234,438. This rejection is respectfully traversed, as the Office Action has failed to state a prima facie case of anticipation.

Claim 10 is directed to a coupler for use in an incontinence procedure utilizing a sling and an elongate needle that is sized and shaped to be initially inserted through an abdominal incision and to then emerge from a vaginal incision, the needle having an insertion end. The claimed coupler comprises an elongate body having an axis, a first end and a second end, and surfaces for conveniently and securely connecting the coupler to the insertion end of the needle by moving the second end of the coupler and the insertion end of the needle together in a substantially axial fashion. After the needle is connected to the coupler, the connected coupler and needle have a Separation Force of at least about fifteen pounds.

Semrad discloses a pulling tip that is attached at one end to a catheter or needle, while the other end is attached to a suture that is used to pull the pulling tip and its attached catheter or needle to its correct subcutaneous location. The pulling tip appears to have a body with a first and second end and some structure for attaching the pulling tip to the catheter or needle. However, Semrad does not disclose that, after the needle is connected to the coupler, the connected coupler and needle have a Separation Force of at least about fifteen pounds. Lacking this limitation, Semrad can not anticipate claim 10.

The official action asserts that “the connector is used to pull a catheter through tissue which would require a separation force of at least fifteen pounds”, stating that this is an inherent quality. Contrary to the official action’s assertion, Applicants’ own research has demonstrated that the force on the present coupler as it moves through animal tissue is between about three and about twelve pounds, less than the fifteen pound force in the claim, and less than the force that the official action alleges the cited prior art must inherently possess. *See* Specification, paragraph 0114, page 23. Semrad states merely that the pulling tip assembly must be formed in such a way as to enable it to be pulled through tissue. Using the Applicants’ research, that would appear to require a force of between three and twelve pounds, less than the claimed fifteen pounds in the present invention, and contrary to the official action’s assertions of inherency.

Further, it appears that the attachment in Semrad is different from the present invention and, resultantly, less secure than the present invention. Semrad teaches that the means for connecting the pulling tip to the catheter consists of a smaller diameter section of the tip, over which the catheter is forced. The present invention, however, shows different structure that would likely result in a stronger connection. In non-limiting examples, Figures 2 through 8 of the present application show embodiments of the coupler of the present invention in which the coupler 54 includes a first end portion 56. The first end portion 56

includes an internal passageway into which the needle is inserted. In other words, the needle and coupler are joined in a way in which the needle is inserted into the coupler, unlike Semrad, in which the catheter is forced over the pulling tip. It is believed that this difference is sufficient to result in the present coupler having superior separation force, greater than fifteen pounds, as compared to Semrad. Lacking disclosure of the limitation that, after the needle is connected to the coupler, the connected coupler and needle have a Separation Force of at least about fifteen pounds, either explicitly or inherently, Semrad is not believed to anticipate the subject matter of claim 10. Consequently, Applicants respectfully request this rejection be withdrawn.

Claims 1-10 were rejected under 35 U.S.C. § 102(e) as anticipated by Lehe, U.S. 6,273,852. These rejections are respectfully traversed, as the Office Action has failed to state a prima facie case of anticipation.

Claim 1 is directed to an assembly for treating incontinence. The assembly includes an elongate needle that is sized and shaped to be initially inserted through an abdominal incision and to then emerge from a vaginal incision, the needle having an insertion end and an end opposite the insertion end. It also includes a sling for implantation in the body, and it includes a coupler having an axis, a first end and a second end. The first and second ends of the coupler have surfaces for conveniently and securely connecting the coupler to the insertion end of the needle by moving the coupler and insertion end of the needle together. Claims 2-9 depend from claim 1 directly or indirectly.

Lehe discloses a surgical instrument and method for treating female urinary stress incontinence. The instrument includes a curved needle-like element with curved shaft, a distal end, and a proximal end. A tape attaches to the needle for implanting into the lower abdomen of a female to provide support to the urethra. The needle and tape may also be modified to allow the surgeon to attach and detach the tape during the surgical operation. Lehe fails to

disclose or suggest a coupler as provided in the present invention. Lacking this limitation, Lehe cannot anticipate the present invention.

The Office Action asserts that the connector 32 of Lehe anticipates the coupler of the present invention. However, this connector lacks significant structure and function found in the present coupler. The connector of Lehe is attached to the sling. *See Lehe*, col. 6, lines 26-28 and figures 2b-2d. Being attached, it has only one end. The coupler defined by claims 1 comprises a first end and a second end. Further, the connector of Lehe does not functionally connect to the insertion end of the needle by moving the connector and the insertion end of the needle together. Instead, Lehe teaches that the connector attaches to the needle by insertion into notches or slots apparently located on the shaft of the needle, not at the insertion end of the needle. *See Lehe*, col. 6 and figures 3a-3f. The connection in Lehe requires insertion of the connector into specially-designed slots by the depression of tab devices. As such, the connection method or apparatus does not appear to involve moving the needle and connector together as in the present invention. There is no teaching or suggestion that the tabs of the connector disclosed in Lehe can be connected to the insertion end of the needle by moving the connector and needle together. As such, Lehe does not anticipate the present invention. Claim 1 and the claims depending therefrom, claims 2-9, should therefore be allowed.

Claims 1-11 were rejected under the doctrine of nonstatutory double patenting over claims 1-15 of U.S. Patent No. 6,641,525. This rejection is obviated by the timely filing of the enclosed properly executed Terminal Disclaimer. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Regarding the objections to the Specification, the Specification is amended by this response. It is believed the outstanding objections have been addressed. No new matter has been added.

Application No. 10/616,938
Reply to Office Action of June 16, 2004

Regarding the Information Disclosure Statements, a corrected copy of the IDS submitted on July 11, 2003 is herein submitted. Earlier inadvertent omissions are corrected.

In light of the above discussion, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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